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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/634,039

Applicant(s)

Snider et al

Examiner

F. Pierre VanderVegt

Group Art Unit

1644



☒ Responsive to communication(s) filed on Jun 6, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-9 ~~is~~are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-9 ~~is~~are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 22

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

Claims 1-9 are currently pending in this application.

#### *Continued Prosecution Application*

- 5 1. The request filed on June 6, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/634,039 is acceptable and a CPA has been established. An action on the CPA follows.
2. In view of the amendment filed June 6, 2000, no outstanding rejections are maintained.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 20 3. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estrada et al (38 on form PTO-1449) in view of McDermott et al (10) and Hamaleers et al (15).

The Estrada et al reference teaches immunization of subjects via the intestinal mucosa using antigen covalently conjugated to anti-MHC Class II antibodies (see entire document). Estrada et al further teaches that these conjugates effectively induce production of IgA and IgG antibodies in mice (Abstract in particular). Estrada et al also teaches that conjugation was effected via the hetero-bifunctional cross-linker SMPB (page 902, first column in particular).

25 Estrada et al does not teach intranasal administration. McDermott et al teaches that the respiratory tract possesses lymphoid aggregates similar to the Peyer's patches (PP) of the intestinal wall (paragraph bridging pages 57 and 58 in particular) termed BALT and that the lymphoepithelium of BALT resembles that of the PP (last paragraph of page 59 in particular).

30 McDermott et al further teaches that BALT is exposed to inhaled antigens because of its location

(last paragraph of page 63 in particular). McDermott et al further teaches that the gut can be viewed as a model for the lung and that studies of oral immunization can provide insight into respiratory tract immunization (page 93, section D in particular). Hamaleers et al teaches that nasal administration of trinitrophenylated (TNP) keyhole limpet hemocyanin (KLH) induced the production of IgA and IgG antibodies to TNP. KLH is commonly used in the art as a carrier for immunogenic haptens, as it is a classical stimulator of helper T cells through classical pathways. Hamaleers et al teaches the administration of the immunogen as liquid drops. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to immunize a subject according to the manner of Hamaleers et al substituting the KLH carrier with an anti-MHC Class II antibody as taught by Estrada et al. One would have been motivated to make the substitution with a reasonable expectation of success based upon the teachings by McDermott et al that the BALT of the respiratory tract is functionally similar to the PP of the intestines and the teachings of Estrada et al that the antibody conjugates specifically targeted the antigen presenting cells in the intestine. One would have been further motivated by the teachings of McDermott et al that local humoral immunity plays an important role in respiratory tract defense against airborne pathogens.

4. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estrada et al (38 on form PTO-1449) in view of McDermott et al (10), Hamaleers et al (15) and Babington, U.S. Patent 4,228,795 (C on form PTO-892).

Estrada et al, McDermott et al and Hamaleers et al have been discussed supra. The combination of references does not teach a disperser for dispersing an aerosol. Hamaleers et al further teaches that a large proportion of aerosolized antigens wind up in the intestines (page 119 in particular). McDermott et al teaches that this is due to swallowing and results in presentation to the immunological apparatus of the intestines (page 48 in particular). The '795 patent teaches a nebulizer which can be used to aerosolize medicants for nasal inhalation (Figure 4 and column 6, line 7 through column 8, line 54 in particular). The '795 patent further teaches that said nebulizer is suitable for use with viscous or sticky substances (column 8, lines 34-37 in particular). It would

have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the nebulizer taught by the '795 patent to administer the mAb-pathogenic antigen conjugate taught by Estrada et al to the nasal mucosa as taught by Hamaleers et al. One would have been motivated, with a reasonable expectation of success to combine these teachings by the desire to elicit an antigen-specific, rather than generalized, response in the mucosa, which is often the first line of encounter of an immune system with pathogenic organisms and by the teachings of the '795 patent that the nebulizer is usable with sticky substances, which a common property of proteinaceous solutions. Further motivation for using the nebulizer of the '795 patent is provided by the knowledge that some individuals do not tolerate nose drops well.


### *Conclusion*

References 1-50 on Applicant's form PTO-1449 filed June 6, 2000 have been lined through as duplicates of references previously cited as references 1-50 on Applicant's form PTO-1449 filed September 16, 1996, which were properly marked as having been considered.

Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
August 18, 2000



F. PIERRE VANDERVEGT  
PATENT EXAMINER